

REMARKS

Status of the Claims.

Claims 1-21 are pending with entry of this amendment, no claims being cancelled and no claims being added herein. Claims 1, and 10-13 are amended herein. This amendment introduces no new matter. Support is replete throughout the specification (*see, e.g.*, page 11, lines 3-6, page 25, lines 10-21, page 34, lines 21-24, Figure 2, and so forth).

35 U.S.C. §112, second paragraph.

Claims 10-13 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. In particular, the Examiner alleged that the phrase "less than about 100 (500) μ m" was indefinite. Claims 10-12 are amended herein to eliminate this language thereby obviating this rejection.

Claim 13 was allegedly indefinite for the recitation of "said two or more analytes" because the recitation allegedly lacks proper antecedent basis in claim 1. Claim 13 is amended to eliminate this language thereby obviating this rejection.

35 U.S.C. §102.

Claims 1-6, 10-17, and 19 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Muscate-Magnussen *et al.* (U.S. Patent No: 6,379,515) hereinafter referred to as "Muscate *et al.*". Applicants traverse.

The Examiner is respectfully reminded that anticipation requires that "all limitations of the claim are found in the reference, or 'fully met' by it." [emphasis added] *Kalman v Kimberly-Clark Corp.*, 218 USPQ 781, 789 (Fed. Cir. 1983).

Claim 1, as amended herein recites:

1. A method of detecting two or more target analytes in a sample, said method comprising:
 - i) providing a channel having affixed therein a first binding partner specific for a first analyte and a second binding partner specific for a second analyte, wherein said first binding partner and said second binding partner are specific for different analytes and, said first binding partner and said second binding partner are located in different regions of said channel, and attached to a wall of said channel, and said channel has a cross-sectional area small enough such that when analytes are released from said first binding partner and said second binding partner into a fluid flowing

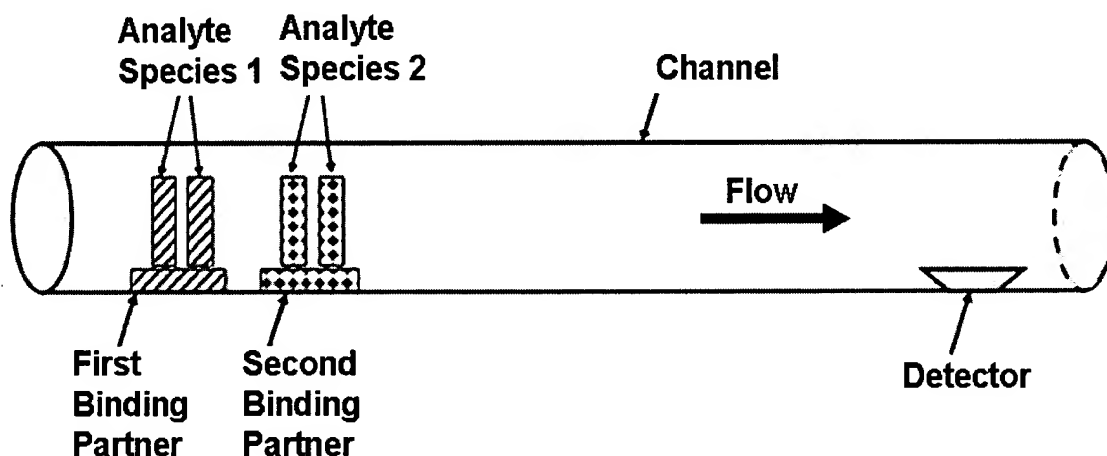
through said channel, said analytes remain spatially segregated until they reach a detection point in said channel downstream from said binding partners;

ii) passing a fluid comprising said sample through said channel under conditions where said target analytes present in said sample bind to their respective binding partners thereby spatially encoding said analytes in said channel;

iii) releasing said analytes from the binding partners into said fluid passing along said channel whereby said analytes are spatially segregated; and

iv) detecting said analytes at a position in said channel downstream from the binding partners. [emphasis added]

As clarified in claim 1, the binding partners are attached to the wall of the channel. One embodiment of this invention showing multiple analytes (analyte species 1, 2) is illustrated schematically below:



Muscate *et al.* fails to disclose or to even suggest method utilizing a device comprising a channel where there are different binding partners in different regions of the channel and binding partners are attached to a wall of the channel.

To the contrary, in the embodiments disclosed by Muscate *et al.*, the binding partners ("receptors") are bound to the polymer gel that fills the electrophoresis tube, not to the walls of the tube. Thus, for example, Muscate *et al.* expressly state:

One object of the invention is a process for the selective separation of electrically charged target molecules in an analytical mixture by means of

capillary affinity gel electrophoresis, using a capillary tube which is at least partly filled with a polymer gel which is solid, or a solution of the polymer in a solvent, having a viscosity of at least 20 mPa·s, whereby receptors for target molecules are covalently bound to the polymer, and an electric field of at least 50 volt/cm is applied, . . . [emphasis added] (col. 3, lines 18-25)

* * *

Polymer gels with covalently bound receptors (hereinafter called immobilised polymers), and their production, are known in large number from affinity gel chromatography, or they may be produced by analogous processes. [emphasis added] (col. 3, lines 49-51)

* * *

The polymers must contain function groups, to which the functionalised receptors may be bound, . . . [emphasis added] (col. 3, lines 61-62)

* * *

The receptors are bound to the spine of the polymer either directly or through a bridging group. Also, such receptors may be bound to the functional terminal groups of a polymer, for example to the hydroxyl group of a polyethylene glycol. The immobilised polymers may be homopolymers or copolymers, which contain the structural elements with covalently bound receptors in a quantity of 0.01 to 99.9, preferably 0.1 to 90, more preferably 0.1 to 60, even more preferably 0.1 to 40, and most preferably 0.1 to 30 % by weight, based on the monomers. It is most preferable to use copolymers, especially those which contain 0.1 to 10, most preferably 0.1 to 5 % by weight of structural elements with covalently bound receptors. [emphasis added] (col. 4, lines 22-34)

Muscate *et al.* offers no disclosure whatsoever of a device comprising a channel (*e.g.* an electrophoresis tube) where binding partners are bound to the wall of the tube. Muscate *et al.* thus fails to provide all of the elements of claim 1 and consequently of dependent claims 2-21. Accordingly, the rejection under 35 U.S.C. §102(e) should be withdrawn.

35 U.S.C. §103(a).

Claims 18 and 21 were rejected under 35 U.S.C. §103(a) as allegedly obvious in light of Muscate *et al.* (*supra*) in view of Muller *et al.* (U.S. Patent No: 5,804,384). The Examiner cited Muscate as disclosing the basic device, but being silent regarding the source of sample. Muller *et al.*

was cited as teaching sources of blood, plasma, serum, urine, oral fluid, cerebrospinal fluid and lymph as well known samples routinely used in various assays. Muller *et al.* was also cited as teaching detection with high sensitivity and without prior amplification. Applicants traverse.

Claim 1, as amended herein, and consequently dependent claims 2-21 all pertain to methods utilizing a device comprising a channel

. . . having affixed therein a first binding partner specific for a first analyte and a second binding partner specific for a second analyte, wherein said first binding partner and said second binding partner are specific for different analytes and, **said first binding partner and said second binding partner are located in different regions of said channel, and attached to a wall of said channel** . . .

The combination of Muscate *et al.* and Muller *et al.* offers no teaching or suggestion of a method using such a device. As explained above- Muscate *et al.* expressly teaches a device wherein the binding partner(s) (receptors) are covalently attached to a polymer. The attachment of the "receptor(s)" to the polymer is not optional. As Muscate *et al.* teaches binding of the receptor(s) to the polymer, this reference effectively teaches away from the device recited in the presently pending claims where the binding partner(s) are attached to a wall of the channel.

Accordingly, the Examiner has failed to make a *prima facie* case, and the rejection of claims 18 and 21 under 35 U.S.C. §103(a) should be withdrawn.

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 337-7871.

QUINE INTELLECTUAL PROPERTY LAW
GROUP, P.C.
P.O. BOX 458
Alameda, CA 94501
Tel: 510 337-7871
Fax: 510 337-7877

Respectfully submitted,



Tom Hunter
Reg. No: 38,498